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hearing is relevant and material and that there were reasonable grounds for the failure to adduce such evidence at the hearing, the entity deciding the appeal may remand the matter to the presiding officer for consideration of the additional evidence.

(j) The Commissioner of Food and Drugs or other entity deciding the appeal (currently the DAB) will issue a decision on the appeal within 60 days, if practicable, of the due date for submission of the appellee's brief. In the decision, the entity deciding the appeal may decline to review the case, affirm the initial decision or decision granting summary decision (with or without an opinion), or reverse the initial decision or decision granting summary decision, or increase, reduce, reverse, or remand any civil money penalty determined by the presiding officer in the initial decision. If the entity deciding the appeal declines to review the case, the initial decision or the decision granting summary decision shall constitute the final decision of FDA and shall be final and binding on the parties 30 days after the declination by the entity deciding the appeal.

(k) The standard of review on a disputed issue of fact is whether the initial decision is supported by substantial evidence on the whole record. The standard of review on a disputed issue of law is whether the initial decision is erroneous.

[60 FR 38626, July 27, 1995, as amended at 71 FR 5979, Feb. 6, 2006]

§ 17.48 Harmless error.

No error in either the admission or the exclusion of evidence, and no error or defect in any ruling or order or in any act done or omitted by the presiding officer or by any of the parties is grounds for vacating, modifying, or otherwise disturbing an otherwise appropriate ruling or order or act, unless refusal to take such action appears to the presiding officer or the Commissioner of Food and Drugs or other entity deciding the appeal (currently the DAB) to be inconsistent with substantial justice. The presiding officer and the entity deciding the appeal at every stage of the proceeding will disregard any error or defect in the proceeding

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that does not affect the substantial rights of the parties.

§ 17.51 Judicial review.

(a) The final decision of the Commissioner of Food and Drugs or other entity deciding the appeal (currently the DAB) constitutes final agency action from which a respondent may petition for judicial review under the statutes governing the matter involved. Although the filing of a petition for judicial review does not stay a decision under this part, a respondent may file a petition for stay of such decision under § 10.35 of this chapter.

(b) The Chief Counsel of FDA has been designated by the Secretary of Health and Human Services as the officer on whom copies of petitions for judicial review are to be served. This officer is responsible for filing the record on which the final decision is based. The record of the proceeding is certified by the entity deciding the appeal (currently the DAB).

(c) Exhaustion of an appeal to the entity deciding the appeal (currently the DAB) is a jurisdictional prerequisite to judicial review.

§ 17.54 Deposit in the Treasury of the United States.

All amounts assessed pursuant to this part shall be delivered to the Director, Division of Financial Management (HFA-100), Food and Drug Administration, rm. 11-61, 5600 Fishers Lane, Rockville, MD 20857, and shall be deposited as miscellaneous receipts in the Treasury of the United States.

PART 19—STANDARDS OF CONDUCT AND CONFLICTS OF INTEREST

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AUTHORITY: 21 U.S.C. 371.

SOURCE: 42 FR 15615, Mar. 22, 1977, unless otherwise noted.

Subpart A—General Provisions

§ 19.1 Scope.

This part governs the standards of conduct for, and establishes regulations to prevent conflicts of interest by, all Food and Drug Administration employees.

§ 19.5 Reference to Department regulations.

(a) The provisions of 45 CFR part 73, establishing standards of conduct for all Department employees, are fully applicable to all Food and Drug Administration employees, except that such regulations shall be applicable to special government employees, i.e., consultants to the Food and Drug Administration, only to the extent stated in subpart L of 45 CFR part 73.

(b) The provisions of 45 CFR part 73a supplement the Department standards of conduct and apply only to Food and Drug Administration employees except special government employees.

§ 19.6 Code of ethics for government service.

The following code of ethics, adopted by Congress on July 11, 1958, shall apply to all Food and Drug Administration employees:

CODE OF ETHICS FOR GOVERNMENT SERVICE

Any person in Government service should:

1. Put loyalty to the highest moral principles and to country above loyalty to persons, party, or Government department.
2. Uphold the Constitution, laws, and legal regulations of the United States and of all governments therein and never be a party to their evasion.
3. Give a full day's labor for a full day's pay; giving to the performance of his duties his earnest effort and best thought.
4. Seek to find and employ more efficient and economical ways of getting tasks accomplished.
5. Never discriminate unfairly by the dispensing of special favors or privileges to any-

one, whether for remuneration or not; and never accept, for himself or his family, favors or benefits under circumstances which might be construed by reasonable persons as influencing the performance of his governmental duties.

6. Make no private promises of any kind binding upon the duties of office, since a Government employee has no private word which can be binding on public duty.

7. Engage in no business with the Government, either directly or indirectly, which is inconsistent with the conscientious performance of his governmental duties.

8. Never use any information coming to him confidentially in the performance of governmental duties as a means for making private profit.

9. Expose corruption wherever discovered.

10. Uphold these principles, ever conscious that public office is a public trust.

§ 19.10 Food and Drug Administration Conflict of Interest Review Board.

(a) The Commissioner shall establish a permanent five-member Conflict of Interest Review Board, which shall review and make recommendations to the Commissioner on all specific or policy matters relating to conflicts of interest arising within the Food and Drug Administration that are forwarded to it by: (1) The Associate Commissioner for Management and Operations or (2) anyone who is the subject of an adverse determination by the Associate Commissioner for Management and Operations on any matter arising under the conflict of interest laws, except a determination of an apparent violation of law. The Director, Division of Ethics and Program Integrity, Office of Management and Operations, shall serve as executive secretary of the Review Board.

(b) It shall be the responsibility of every Food and Drug Administration employee with whom any specific or policy issue relating to conflicts of interest is raised, or who otherwise wishes to have any such matter resolved, to forward the matter to the Associate Commissioner for Management and Operations for resolution, except that reporting of apparent violations of law are governed by § 19.21.

(c) All general policy relating to conflicts of interest shall be established in guidance documents pursuant to the provisions of § 10.90(b) of this chapter and whenever feasible shall be incorporated in regulations in this subpart.

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(d) All decisions relating to specific individuals shall be placed in a public file established for this purpose by the Freedom of Information Staff, e.g., a determination that a consultant may serve on an advisory committee with specific limitations or with public disclosure of stock holdings, except that such determination shall be written in a way that does not identify the individual in the following situations:

(1) A determination that an employee must dispose of prohibited financial interests or refrain from incompatible outside activities in accordance with established Department or agency regulations.

(2) A determination that a proposed consultant is not eligible for employment by the agency.

(3) A determination that public disclosure of any information would constitute an unwarranted invasion of personal privacy in violation of § 20.63 of this chapter.

[42 FR 15615, Mar. 22, 1977, as amended at 46 FR 8456, Jan. 27, 1981; 50 FR 52278, Dec. 23, 1985; 55 FR 1404, Jan. 16, 1990; 65 FR 56479, Sept. 19, 2000]

Subpart B—Reporting of Violations

§ 19.21 Duty to report violations.

(a) The Office of Internal Affairs, Office of the Commissioner, is responsible for obtaining factual information for the Food and Drug Administration on any matter relating to allegations of misconduct, impropriety, conflict of interest, or other violations of Federal statutes by agency personnel.

(b) Any Food and Drug Administration employee who has factual information showing or who otherwise believes that any present or former Food and Drug Administration employee has violated or is violating any provision of this subpart or of 45 CFR parts 73 or 73a or of any statute listed in appendix A to 45 CFR part 73 should report such information directly to the Office of Internal Affairs. Any such reports shall be in writing or shall with the assistance of the Office of Internal Affairs, be reduced to writing, and shall be promptly investigated.

(c) Any report pursuant to paragraph (b) of this section and any records relating to an investigation of such re-

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ports shall be maintained in strict confidence in the files of the Office of Internal Affairs, shall be exempt from public disclosure, and may be reviewed only by authorized Food and Drug Administration employees who are required to do so in the performance of their duties.

[42 FR 15615, Mar. 22, 1977, as amended at 46 FR 8456, Jan. 27, 1981; 50 FR 52278, Dec. 23, 1985; 60 FR 47478, Sept. 13, 1995]

Subpart C—Disqualification Conditions

§ 19.45 Temporary disqualification of former employees.

Within 1 year after termination of employment with the Food and Drug Administration, no former Food and Drug Administration employee, including a special government employee, shall appear personally before the Food and Drug Administration or other federal agency or court as agent or attorney for any person other than the United States in connection with any proceeding or matter in which the United States is a party or has a direct and substantial interest and which was under his official responsibility at any time within one year preceding termination of such responsibility. The term *official responsibility* means the direct administrative or operating authority, whether intermediate or final, and either exercisable alone or with others, and either personally or through subordinates, to approve, disapprove, or otherwise direct government action.

§ 19.55 Permanent disqualification of former employees.

No former Food and Drug Administration employee, including a special government employee, shall knowingly act as agent or attorney for anyone other than United States in connection with any judicial or other proceeding, application, request for a ruling or other determination, contract, claim, controversy, charge, accusation, or other particular matter involving a specific party or parties in which the United States is a party or has a direct and substantial interest and in which he participated personally and substantially through decision, approval, disapproval, recommendation, rendering

of advice, investigation, or otherwise as a Food and Drug Administration employee.

PART 20—PUBLIC INFORMATION

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- 20.1 Testimony by Food and Drug Administration employees.
- 20.2 Production of records by Food and Drug Administration employees.
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- 20.29 Prohibition on withdrawal of records from Food and Drug Administration files.
- 20.30 Food and Drug Administration Freedom of Information Staff.
- 20.31 Retention schedule of requests for Food and Drug Administration records.
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- 20.40 Filing a request for records.
- 20.41 Time limitations.
- 20.42 Aggregation of certain requests.
- 20.43 Multitrack processing.
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- 20.48 Judicial review of proposed disclosure.
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- 20.60 Applicability of exemptions.
- 20.61 Trade secrets and commercial or financial information which is privileged or confidential.
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- 20.63 Personnel, medical, and similar files, disclosure of which constitutes a clearly unwarranted invasion of personal privacy.
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- 20.67 Records exempted by other statutes.

Subpart E—Limitations on Exemptions

- 20.80 Applicability of limitations on exemptions.
- 20.81 Data and information previously disclosed to the public.
- 20.82 Discretionary disclosure by the Commissioner.
- 20.83 Disclosure required by court order.
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- 20.85 Disclosure to other Federal government departments and agencies.
- 20.86 Disclosure in administrative or court proceedings.
- 20.87 Disclosure to Congress.
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Subpart F—Availability of Specific Categories of Records

- 20.100 Applicability; cross-reference to other regulations.
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- 20.105 Testing and research conducted by or with funds provided by the Food and Drug Administration.
- 20.106 Studies and reports prepared by or with funds provided by the Food and Drug Administration.
- 20.107 Food and Drug Administration manuals.
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- 20.109 Data and information obtained by contract.